Translation and ISO 13485:2016

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How do translations fit into your quality management system? A vital (but often overlooked) component to your device, translations are frequently sourced based on price or the provider's ability to deliver translated documents quickly. Once a translation supplier is on board, many organizations never re-qualify that provider or research alternatives that may be better suited for the organization's long-term needs. As you upgrade your quality system to the 2016 revision of the ISO 13485 standard, you may want to take the opportunity to consider translations more deeply and determine whether your current translation supplier is ready for greater oversight.

This brief looks at several key provisions of ISO 13485:2016 that you should consider in selecting and managing a translation provider. In particular, we look at:

- **Planning**: what you should do before selecting a supplier.
- **Purchasing**: considerations for setting up a new supplier.
- **Monitoring**: how to ensure the supplier consistently performs to your team's expectations.

Evaluating Risk

ISO 13485:2016, Clause 4.1.5

"When the organization chooses to outsource any process that affects product conformity to requirements, it shall monitor and ensure control over such processes…The controls shall be proportionate to the risk involved and the ability of the external party to meet the requirements…"

Generally speaking, your organization must monitor and control any outsourced process, and translation is no exception. The key question from any auditor will be "What effect does this supplier have on the quality of the medical device?" For instance, a translation error in your instructions for use or a recall notice carries a very high risk. The translation process for these types of documents must, therefore, be carefully controlled.

You will also need to consider the ability of your organization to verify the translated content. If you have an in-country stakeholder who can read the translation and give it a "thumbs up," you already have better control over the translation process than if you are merely doing a quick check that all bullet points are accounted for in the list of contraindications. Make sure that whatever verification process you use adds value and doesn't become a resource drain*. For some guidelines on how to use an in-country review to improve quality, check out this brief.

***Be Wary of Validation by Distributors**

What happens if your internal processes require in-country review of translations, but you don't have a key stakeholder in every market? Many organizations choose to use distributors to review translations. If you take this route, make sure you consider the downside. Translation review is not a primary service offered by most distributors, so you will be asking them to provide a service that is outside their standard offering. This can often mean that they either rubber stamp the translation (which is clearly not your intention) or they put it on the backburner (which slows down your project timeline). A distributor also cannot add the same kind of value to the in-country review process that a key stakeholder can. A key stakeholder will know the "lingo" used by your local team for the device and he or she can share this terminology with your translation provider so that your provider begins to "talk" the same way as your local team.

Another key consideration of ISO 13485:2016 is the ability of a supplier to meet requirements. So what are your requirements for a translation provider? If your team hasn't worked extensively with translations before, this can be difficult to define. You will certainly want to consider:

- experience with medical device translations
- languages offered and whether these align with your international plans
- responsiveness to your requests
- robustness of the translation process, including what process checks and balances are in place to prevent errors
- quality system certifications.

Risk: Questions for Your Team

- ✓ What kinds of documents will you need translated? What is the risk profile for these documents and for the associated device(s)?
- ✓ What verification processes are available in your organization?
- ✓ What requirements have you already defined for translation providers?
- ✓ Are there any additional requirements you should consider that would improve translation quality?

Establishing the Relationship

ISO 13485:2016, Clause 7.4.2

"The organization shall ensure the adequacy of specified purchasing requirements prior to their communication to the supplier."

Once you have determined that a particular translation provider is the right fit, it is important to define the relationship with a written quality agreement. The template that you use for other suppliers, such as component part manufacturers, will likely not be applicable to translation services. Here are some key elements to consider for a translation-oriented quality agreement:

- What quality system certifications must the supplier maintain (ISO 9001, ISO 13485, ISO 17100)?
- What process requirements are in place for each translation (independent editing, quality control, etc.) and how many pairs of eyes must look at each project?
- What competencies are required for personnel working on your projects?**
- What are your expectations for the provider's ability to handle complaints/SCARS?

Beyond the formal requirements, how do you ensure that you have adequately communicated all your requirements (including the ones you might not think to specify, such as consistency with translations that are already in circulation)? Be transparent and share knowledge. Make sure

****Defining Competencies**

Your team makes a medical device. So how do you know what competencies are required for translation personnel? Thankfully, the International Standards Organization is here to help. In 2015, ISO adopted ISO 17100, which defines requirements for translation services, including personnel competencies. Many translation providers claim "compliance," but make sure you select one who has been independently audited and certified to the standard. While you're at it, get a copy of the provider's certificate for your records.

your translation provider knows:

- What translations you have done in the past (so they can be consistent with the terminology).
- What issues you've had in the past (so they don't repeat them).
- Where your organization is going (so they can optimize your documentation and ensure they have the resources for languages you will be requesting down the road).

Relationship: Questions for Your Team

- ✓ What are the high level requirements for any translation provider to work with your organization?
- ✓ Where have you encountered problems in the past and how can you communicate those to a provider to avoid recurrence?
- ✓ What translation needs are on the horizon for the next few years?
- ✓ Do you have a quality agreement in place with any current translation providers?

Monitoring the Supplier

ISO 13485:2016, Clause 7.4.3

"The organization shall establish and implement the inspection or other activities necessary for ensuring that purchased product meets specified purchase requirements. The extent of verification activities shall be based on the supplier evaluation results and proportionate to the risks associated with the purchased product."

Depending upon the risk profile of the document and the resources available to your team, there are many different ways to define a verification and evaluation program for translation providers. For instance, you might:

1. Establish minimum quality system requirements for the translation provider and then take a reactive approach by monitoring complaints from international users. This places the monitoring burden on your Quality department to audit the translation provider.
2. Do a side-by-side comparison of each completed translation to confirm all elements are present, even if your team cannot speak the language. This requires a bit of additional quality control time for each project, but is especially valuable before sending anything to be physically printed.
3. Send translations to in-country review by a key stakeholder before they are finalized. When properly run, an in-country review offers the best value-add way to monitor the performance of your translation provider. Be careful, though, to establish guidelines about what kinds of content require review and what documents can undergo a less robust verification. If you have a highly qualified provider and a super-hot recall notice that needs to be distributed to your international customers immediately, you probably don't want to lose the additional time on an in-country review.

The key is to make sure you build a process that provides the level of oversight you need but does not bog your team down with too many requirements, which will only serve to compress timelines and force your translation provider to work too fast to create a quality translation. And if your provider is not delivering, don't be afraid to make a change. There are translation providers who specialize in serving medical device clientele and will understand the challenges specific to your organization.

Monitoring: Questions for Your Team

- ✓ How do you verify that translations meet your specified requirements?
- ✓ Do you inform your translation provider about every translation complaint you receive?
- ✓ If your in-country team wants to make changes to the translation, do you involve your translation provider so they can improve their services to you while confirming that suggested changes don't raise additional problems to resolve?
- ✓ When performance falls short, what are the consequences? When do you take action on a trend of negative performance?

Summary

The newest revision of ISO 13485 has increased expectations on medical device manufacturers to control outsourced processes and verify purchased product. When looking at translations, this means evaluating suppliers against objective criteria to make certain that the supplier will meet your team's requirements, establishing quality agreements that hold them accountable, and communicating openly when requirements are not met. A good translation provider should be a good partner, helping your team reduce the risks associated with your translated documentation and supporting your team's international activities.

About Idem Translations

Founded in 1983, Idem Translations, Inc. is a full-service provider of translation and localization services. Idem specializes in certified translations for medical device, biomedical, and pharmaceutical companies, as well as other organizations and entities working in the life sciences sector, such as contract research organizations, healthcare research centers, and institutional review boards. The company is a WBENC-certified woman-owned business and holds certifications to ISO 9001:2015, ISO 13485:2003, and ISO 17100:2015.

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